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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | | |
|---|-------------|----------------------------|-----------------------|---------------------------|--|--|
| 10/731,379 | 12/09/2003 | Daniel Zamanillo Castanedo | P03,0588 (29478-0015) | 4441 | | |
| 26574 | 7590 | 08/19/2008 | EXAMINER | | | |
| SCHIFF HARDIN, LLP PATENT DEPARTMENT 6600 SEARS TOWER CHICAGO, IL 60606-6473 | | | | HIRIYANNA, KELAGINAMANE T | | |
| ART UNIT | | PAPER NUMBER | | | | |
| 1633 | | | | | | |
| MAIL DATE | | DELIVERY MODE | | | | |
| 08/19/2008 | | PAPER | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|---------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/731,379 | CASTANEDO ET AL. |
| | Examiner | Art Unit |
| | KELAGINAMANE T. HIRIYANNA | 1633 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 31 March 2008.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-3,5,6,8,9,14-21,28 and 29 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-3, 5-6, 8-9, 14-21, 28-29 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
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| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Applicant's response filed on 03/31/2008 in response to office action mailed on 12/31/2007 has been acknowledged.

Claims 31 and 32 are cancelled.

Claims 1-3, 5-6, 8-9, 14-21, 28-29, are pending and are examined in this office action.

Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.

Withdrawn: Objection made under 37 CFR 1.75 regarding duplicate claims as set forth in the previous office action of record dated 12/31/2007 has been withdrawn in view of Applicants cancelling of the cited duplicate claims 31 and 32.

Claim Rejection 35 USC § 112 (2nd paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1, 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

While the base claim 1 recites on line 1 as "mouse deficient in an endogenous Sigma-receptor" and further recites on line 4 as "giving rise to a transgenic mouse lacking detectable levels of endogenous Sigma-1 receptor" the dependent Claim 2 contains the limitation on line 2 "the mouse is a heterozygous mutant for said mutation". The

dependent claim limitation is thus inconsistent with the mouse claimed in base claim as well as the results shown in Figure 13 of the specification where it clearly depicts the heterozygous mouse (+/-) expressing detectable levels of said protein. Thus it makes it unclear if such limitation is meant to limit the claim or not. Hence, the claims are rejected for indefiniteness.

Claims 3, 5-6, 8, 17-21, 28-29 are objected-to as they are dependent from rejected base claim.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the recitation in lines 15-16 is not properly connected to statement on line 1-2.

Claims 14-15 are objected-to as they are dependent from a rejected claim.

Claim Rejection 35 USC § 112 (1st paragraph)

Claims 1-3, 5-6, 8-9, 14-21, 28-29, stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's referral to the deposit of the vector identified as pHR53TK that is deposited in the CECT under access number CECT5737 used for generating a disruption in a gene of an endogenous Sigma-1 receptor of mouse in the claims and the specification is insufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met. Therefore one skill in the art would not be able to exercise the invention as claimed.

If the deposit was made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by Applicant, Assignee, or a statement by an attorney of record over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository, is required. This requirement is necessary when a deposit is made under the provisions of the Budapest Treaty, as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and address of the depository is required.

Furthermore, unless deposit was made at or before the time of filing, a declaration filed under 37 CFR 1.132 is necessary to construct a chain of custody. The declaration, executed by a person in a position to know, should identify the deposited material by its depository accession number, establish that the deposited material is the same as that described in the specification, and establish that the deposited material was in Applicant's possession at the time of filing. See *In re Lundak*, 27 USPQ 90.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request, or for the enforceable life of the patent, whichever is longer;

- d) a test of the viability of the biological material at the time of the deposit was made, and that the test results indicated that said biological material was viable (see 37 CFR 1.807); and,
- e) the deposit will be replaced it should ever become inviable.

Applicant's attention is directed to M.P.E.P 2400 in general, and specifically to 2411.05, as well as 37 C.F.R. 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." The specification should be amended to include this information, however, Applicant is cautioned to avoid the entry of new matter into the specification by adding any other information.

Response to Applicants arguments of 03/31/2008:

The applicants argues that a biological deposit form that meets the "Budapest treaty requirement" has been filed but has some how got included under the description of "NPL Documents" category in the office and hence the rejection under 112 (1st paragraph) as stated in the previous office action be withdraw.

The Applicants arguments are fully considered and found persuasive with respect to filing of a Biological Deposit form that meets the "Budapest Treaty" and that indicates a date of 05 Jan 2006. However, since the date of certification is well beyond the date of filing the Applicant may provide a declaration filed under 37 CFR 1.132 is necessary to construct a chain of custody. The declaration, executed by a person in a position to know, should identify the deposited material by its depository accession number, establish that the deposited material is the same as that described in the specification, and establish that the deposited material was in Applicant's possession at the time of filing. See *In re Lundak*, 27 USPQ 90.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may

provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request, or for the enforceable life of the patent, whichever is longer;
- d) a test of the viability of the biological material at the time of the deposit was made, and that the test results indicated that said biological material was viable (see 37 CFR 1.807); and,
- e) the deposit will be replaced if it should ever become inviable.

Conclusion:

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanne Ph.D.*, whose telephone number is **(571) 272-3307**. The examiner can normally be reached Monday through Thursday from 9 AM-7PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach Ph.D.*, may be reached at **(571) 272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

Kelaginamane T. Hiriyanna

Patent Examiner

Art Unit 1633

/Robert M Kelly/

Examiner of Art Unit 1633

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| Examiner KELAGINAMANE T. HIRIYANNA | Art Unit 1633 | |